

WHAT IS CLAIMED IS:

Sub P1

1. A pharmaceutical composition in a closed container, said composition comprising a meiosis activation substance having a low oxygen content, and wherein said closed container is capable of maintaining the low content of oxygen.

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2. The pharmaceutical composition in a closed container according to claim 1, wherein the low oxygen content is below about 0.01 moles oxygen per liter of the volume of the container.

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3. The pharmaceutical composition in a closed container according to claim 1, wherein the low oxygen content is below about 0.001 moles of oxygen per liter of the volume of the container.

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4. The pharmaceutical composition in a closed container according to claim 1, wherein the low oxygen content is below about 0.0001 moles of oxygen per liter of the volume of the container.

5. A pharmaceutical composition in a closed container comprising:

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(i) a solid composition of a meiosis activation substance,

(ii) an additive,

(iii) an atmosphere with a low oxygen content, and

wherein the closed container is capable of maintaining the low content of oxygen.

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6. The pharmaceutical composition in a closed container according to claim 5, wherein the solid composition of a meiosis activation substance has a high aqueous solubility.

7. The pharmaceutical composition in a closed container according to claim 5, wherein the oxygen content of the atmosphere is below 10%.

5 8. The pharmaceutical composition in a closed container according to claim 5, wherein the oxygen content of the atmosphere is below 5%.

9. The pharmaceutical composition in a closed container according to claim 5, wherein the oxygen content of the atmosphere is below 1%.

10 10. The pharmaceutical composition in a closed container according to claim 5, wherein the atmosphere contains over 90% nitrogen or argon.

15 11. The pharmaceutical composition in a closed container according to claim 5, wherein the atmosphere contains over 99% nitrogen or argon.

12. The pharmaceutical composition in a closed container according to claim 5, wherein the solid composition has a water content below about 10%.

20 13. The pharmaceutical composition in a closed container according to claim 5, wherein the solid composition has a water content below about 5%.

14. The pharmaceutical composition in a closed container according to claim 5, wherein the solid composition has a water content below about 1%.

25 15. The pharmaceutical composition in a closed container according to claim 5, wherein the solid composition has an organic solvent content below about 10%.

16. The pharmaceutical composition in a closed container according to claim 5, wherein the solid composition has an organic solvent content below about 5%.

17. The pharmaceutical composition in a closed container according to claim 5, wherein the solid composition has an organic solvent content below about 1%.

5 18. The pharmaceutical composition in a closed container according to claim 5, wherein the meiosis activation substance content is below about 10% by weight.

10 19. The pharmaceutical composition in a closed container according to claim 5, wherein the meiosis activation substance content is below about 2% by weight.

20. The pharmaceutical composition in a closed container according to claim 5, wherein the meiosis activation substance content is below about 1% by weight.

15 21. The pharmaceutical composition in a closed container according to claim 1, wherein the meiosis activation substance is a compound exhibiting a percentage germinal vesicle breakdown which is 50% higher than a control.

20 22. The pharmaceutical compositions in a closed container according to claim 1, wherein the meiosis activation substance is selected from 4,4-dimethyl-5 α -cholesta-8,14,24-triene-3 β -ol; 4,4-dimethyl-5 α -cholest-8,14,24-trien-3 β -ol hemisuccinate; 5 α -cholest-8,14-dien-3 β -ol; 5 α -cholest-8,14-dien-3 β -ol hemisuccinate; (20S)-cholest-5-en-3 β ,20-diol; 3 β -hydroxy-4,4-dimethyl-5 α -chola-8,14-dien-24-oic acid-N-(methionine) amide; cholest-5-en-16 β -ol; and (20S)-20-[(piperidin-1-yl)methyl]-4,4-dimethyl-5 α -pregna-8,14-dien-3 β -ol.

25 23. The pharmaceutical composition in a closed contained according to claim 5, wherein the additive is a protein or a phosphorglyceride.

24. The pharmaceutical composition in a closed container according to claim 23, wherein the protein is serum albumin.

25. The pharmaceutical composition in a closed container according to claim 24, wherein the serum albumin is human serum albumin or recombinant form human serum albumin.

5 26. The pharmaceutical composition in a closed container according to claim 5, wherein the additive content is above about 90%.

27. The pharmaceutical composition in a closed container according to claim 5, wherein the additive content is above about 98%.

10 28. The pharmaceutical composition in a closed container according to claim 5, wherein the additive content is above about 99%.

29. The pharmaceutical composition in a closed container according to claim 5, said container having one or more hollow spaces and wherein at least one hollow spaces contains

15 (i) the solid composition of a meiosis activation substance with a high aqueous solubility,

(ii) the additive, and

(iii) the atmosphere with a low oxygen content.

20 30. The pharmaceutical composition in a closed container according to claim 5, wherein an aqueous media is added to the solid composition to form an aqueous solution.

31. The pharmaceutical composition in a closed container according to claim 30,

25 wherein the meiosis activation substance in the aqueous solution is in a concentration above about 100 µg/ml.

32. The pharmaceutical composition in a closed container according to claim 30,

30 wherein the meiosis activation substance in the aqueous solution is in a concentration above about 10 µg/ml.

33. The pharmaceutical composition in a closed container according to claim 30, wherein the meiosis activation substance in the aqueous solution is in a concentration above about 1 μ g/ml.

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34. The pharmaceutical composition in a closed container according to claim 30, wherein the meiosis activation substance in the aqueous solution is in a concentration above about 0.001 μ g/ml.

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35. The pharmaceutical composition in a closed container according to claim 30, wherein the aqueous media has an organic solvent content of less than about 0.1%.

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36. The pharmaceutical composition in a closed container according to claim 30, wherein the aqueous media has an organic solvent content of less than about 0.05%.

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37. A process for preparing a pharmaceutical composition in a closed container, comprising
a) preparing a solid composition comprising a meiosis activation substance and an additive;
b) adding the solid composition to the container;
c) freeze drying the composition; and
d) closing the container *in vacuo*.

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38. The process according to claim 37, wherein the preparation of the solid composition is performed *in vacuo*.

39. The process according to claim 37, wherein the preparation of the solid composition is in an atmosphere having a low content of oxygen.

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40. A process for preparing a pharmaceutical composition in a closed container, said process comprising:

- a) preparing a solid composition comprising a meiosis activation substance and an additive;
- b) filling the solid composition into the container;

5 c) filling the container with an atmosphere having a low content of oxygen; and

d) closing the container.

41. The process according to claim 40, wherein the solid composition is prepared in an atmosphere having a low content of oxygen.

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42. A process for increasing the stability of a pharmaceutical composition in a closed container comprising:

- a) preparing a solid composition comprising a meiosis activation substance having a low content of oxygen and an additive;

15 b) filling the solid composition into the container;

c) filling the container with an atmosphere having a low content of oxygen; and

d) closing the container.

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